



212/083

Patent

CP 180

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#10

In re Application of:

Hogan et al.

Serial No. 08/454,529

Filed: May 30, 1995

For: NUCLEIC ACID PROBES FOR  
DETECTION AND/OR  
QUANTITATION OF NON-VIRAL  
ORGANISMS

Group Art Unit 1809

Examiner: Marschel, A

RECEIVED  
JAN 17 1997  
GROUP 1800

37 C.F.R. § 1.48(c) PETITION TO AMEND INVENTORSHIPAssistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Applicants hereby petition that the inventorship of the above-captioned application be amended so that JoAnn Kop and Sherrol Hoffa McDonough are added as inventors. Due to the amendment to the claims filed September 3, 1996, contributions of JoAnn Kop and Sherrol Hoffa McDonough are now being claimed in the application. The application

## CERTIFICATE OF MAILING

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

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12-17-96

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date of deposit

JAN ROSE  
name of person mailing paper

JAN ROSE  
signature of person mailing paper

SSSD/26154. v01

250 WJ 12-9475 01/10/97 08454529  
21097 1:2 130.00CH

should list James John Hogan, Richard Dana Smith, JoAnn Kop, and Sherrol Hoffa McDonough as inventors.

The present application was filed on May 30, 1995 listing James John Hogan and Richard Dana Smith as inventors. On July 8, 1996, Applicants amended and added new claims referencing different target regions. JoAnn Kop and Sherrol Hoffa McDonough contributed to subject matter in one or more of the amended and new claims.

Applicant's representative recently recognized the need to amend inventorship upon reviewing the file. The failure to amend the inventorship when filing the amendment dated on September 3, 1996 was made without any deceptive intent.

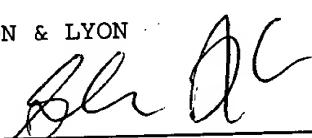
Submitted herewith in support of this petition for correction of inventorship, is a Declaration by James John Hogan, Richard Dana Smith, JoAnn Kop, and Sherrol Hoffa McDonough; a newly executed Oath and Power of Attorney; written consent of the assignee to the change in inventorship; and a certificate under 37 C.F.R § 3.73 (b).

Please charge Deposit Account No. 12-2475 \$130.00 to cover fees associated with the present petition. If this amount is incorrect please charge Deposit Account No. 12-2475 the appropriate amount for any fees due in connection with this petition.

Respectfully submitted,

LYON & LYON

By

  
Sheldon O. Heber

Reg. No. 38,179

First Interstate World Center  
633 West Fifth Street, 47th Floor  
Los Angeles, CA 90071-2066  
San Diego (619) 552-8400

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Hogan et al.

Serial No. 08/454,529

Filed: May 30, 1995

For: NUCLEIC ACID PROBES FOR  
DETECTION AND/OR  
QUANTITATION OF NON-VIRAL  
ORGANISMS

Group Art Unit 1819

Examiner: Marschel, A

RECEIVED  
JAN 17 1997  
GROUP 1800

Declaration of James John Hogan, Richard Dana Smith, JoAnn Kop, and  
Sherrol Hoffa McDonough

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

We, James John Hogan, Richard Dana Smith, JoAnn Kop, and Sherrol Hoffa McDonough declare as follows:

1. This declaration supports the accompanying Petition under 37 C.F.R. § 1.48(c) to Correct Inventorship of the above-captioned patent application. To the extent the following declarations relate to acts of persons other than the respective declarants, the declarations are made on information and belief.

2. The above-captioned patent application was filed on May 30, 1995, indicating that James John Hogan and Richard Dana Smith should be listed as inventors.

3. On September 3, 1996, amended and new claims were added referencing different target regions. JoAnn Kop and Sherrol Hoffa

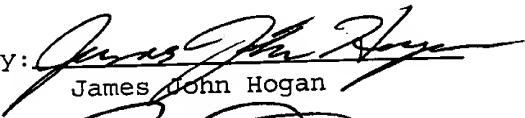
McDonough contributed to the subject matter in one or more of the amended and new claims.

4. Applicant's representative recently recognized the need to amend inventorship upon reviewing the file and pending claims for the above-captioned application. The failure to amend the inventorship when filing the amendment dated September 3, 1996 was made without any deceptive intent.

5. Declarants have reviewed the amendment filed September 3, 1996, and believe that the present application as amended on September 3, 1996, should list James John Hogan, Richard Dana Smith, JoAnn Kop, and Sherrol Hoffa McDonough as inventors.

We hereby declare that all statements made herein of our own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application and any patent issuing thereon.

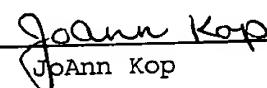
Date: 11/27/96

By:   
James John Hogan

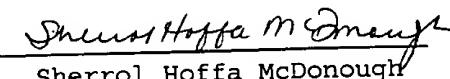
Date: 12/11/96

By:   
Richard Dana Smith

Date: 11/7/96

By:   
JoAnn Kop

Date: 12-6-96

By:   
Sherrol Hoffa McDonough



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**COMBINED DECLARATION AND POWER OF ATTORNEY**  
(Continuation or CIP Application)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled NUCLEIC ACID PROBES FOR DETECTION AND/OR QUANTITATION OF NON-VIRAL ORGANISMS the specification of which

is attached hereto.

x was filed on May 30, 1995, as Application Serial No. 08/454,529 and was amended on May 30, 1995 and September 3, 1996

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s):

(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

<u>08/200,866</u> (Application Serial No.)	<u>February 22, 1994</u> (Filing Date)	<u>U.S. Patent 5,541,308</u> (Status) (patented, pending, abandoned)
<u>07/806,929</u> (Application Serial No.)	<u>December 11, 1991</u> (Filing Date)	<u>Abandoned</u> (Status) (patented, pending, abandoned)
<u>07/295,208</u> (Application Serial No.)	<u>December 9, 1988</u> (Filing Date)	<u>Abandoned</u> (Status) (patented, pending, abandoned)
<u>PCT/US87/03099</u> (Application Serial No.)	<u>November 24, 1987</u> (Filing Date)	<u> </u> (Status) (patented, pending, abandoned)
<u>07/083,542</u> (Application Serial No.)	<u>August 7, 1987</u> (Filing Date)	<u>Abandoned</u> (Status) (patented, pending, abandoned)
<u>06/934,244</u> (Application Serial No.)	<u>November 24, 1986</u> (Filing Date)	<u>Abandoned</u> (Status) (patented, pending, abandoned)

As a named inventor, I hereby appoint as my attorneys, with full power of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

Roland N. Smoot, Reg. No. 18,718; Conrad R. Solum, Jr. Reg. No. 20,467; James W. Geriak, Reg. No. 20,233; Robert M. Taylor, Jr., Reg. No. 19,848; Samuel B. Stone, Reg. No. 19,297; Douglas E. Olson, Reg. No. 22,798; Robert E. Lyon, Reg. No. 24,171; Robert C. Weiss, Reg. No. 24,939; William E. Thomson, Jr., Reg. No. 29,719; Richard E. Lyon, Jr., Reg. No. 26,300; John D. McConaghy, Reg. No. 26,773; William C. Steffin, Reg. No. 26,811; Coe A. Bloomberg, Reg. No. 26,605; J. Donald McCarthy, Reg. No. 25,119; John M. Benassi, Reg. No. 27,483; Roy James H. Shalek, Reg. No. 29,749; Allan W. Jansen, Reg. No. 29,395; Robert W. Dickerson, Reg. No. 29,914; Roy L. Anderson, Reg. No. 30,240; David B. Murphy, Reg. No. 31,125; James C. Brooks, Reg. No. 29,898; Jeffrey M. Olson, Reg. No. 30,790; Steven D. Hemminger, Reg. No. 30,755; Jerrold B. Reilly, Reg. No. 32,293; Paul H. Meier, Reg. No. 32,274; John A. Rafter, Jr., Reg. No. 31,653; Kenneth H. Ohriner, Reg. No. 31,646; Mary S. Consalvi, Reg. No. 32,212; Bradford J. Duft, Reg. No. 32,219; and Sheldon O. Heber, Reg. No. 38,179 of LYON & LYON, 633 West Fifth Street, Suite 4700, Los Angeles, California 90071-2066 telephone (619) 552-8400.

Address all telephone calls to Sheldon O. Heber, Esq. at telephone no. (619) 552-8400  
 Address all correspondence to Sheldon O. Heber, Esq., LYON & LYON, 633 West Fifth Street, Suite 4700, Los Angeles, CA 90017-2066.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

Full name of sole or first inventor James John Hogan

Inventor's signature James John Hogan Date: 11/27/96

Residence Coronado, California

Citizenship United States of America

Post Office Address 1038 Olive Lane, Coronado, California 92118

Full name of second inventor Richard Dana Smith

Inventor's signature Richard Dana Smith Date: 12/11/96

Residence Victoria, British Columbia, Canada

Citizenship United States of America

Post Office Address 890 Denford Crescent, Victoria, British Columbia, Canada V8X4N1

Full name of third inventor JoAnn Kop

Inventor's signature JoAnn Kop Date: 11/7/96

Residence Fremont, California, United States of America

Citizenship United States of America

Post Office Address 36101 Malta Place, Fremont, California 94536

Full name of fourth inventor Sherrol Hoffa McDonough

Inventor's signature Sherrol Hoffa McDonough Date: 12-6-96

Residence San Diego, California, Untied States of America

Citizenship United States of America

Post Office Address 5005 Maynard Street, San Diego, California 92122

## APPLICABLE STATUTES & RULES

### 37 CFR 1.56 DUTY TO DISCLOSE INFORMATION MATERIAL TO PATENTABILITY.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by 37 CFR 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of foreign patent offices in a counterpart application, and
  - (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.
- (b) Under this section information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim;
  - (2) It refutes, or is inconsistent with, a position the applicant takes in;
  - (3) Opposing an argument of unpatentability relied on by the Office, or
  - (4) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
  - (2) Each attorney or agent who prepared or prosecutes the application; and
  - (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.
- (d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

### 35 U.S.C. 102. CONDITIONS FOR PATENTABILITY; NOVELTY AND LOSS.

#### OF RIGHT TO PATENT

A person shall be entitled to a patent unless--

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
- (c) he has abandoned the invention, or
- (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or
- (f) he did not himself invent the subject matter sought to be patented, or
- (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

### 35 U.S.C. 103. CONDITIONS FOR PATENTABILITY; NON-OBVIOUS

#### SUBJECT MATTER

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

### 35 U.S.C. 119. BENEFIT OF EARLIER FILING DATE IN FOREIGN COUNTRY; RIGHT OF PRIORITY (Applicable Portion)

An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed, but no patent shall be granted on any application for a patent for an invention which has been patented or described in a printed publication in any country more than one year before the date of the actual filing of the application in this country, or which had been in public use or on sale in this country more than one year prior to such filing.

### 35 U.S.C. 120. BENEFIT OF EARLIER FILING DATE IN THE UNITED STATES

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, by the same inventor shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

### 35 U.S.C. 112. SPECIFICATION (Applicable Portion)

The specification shall contain a written description of the invention, and of the making and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctive claiming the subject matter which the applicant regards as his invention.



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CERTIFICATE UNDER 37 C.F.R. SECTION 3.73(b)

Applicant: Hogan, et al.

Application No.: 08/454,529

Filed: May 30, 1995

For: NUCLEIC ACID PROBES FOR DETECTION AND/OR QUANTITATION OF NON-VIRAL ORGANISMS

Gen-Probe Incorporated a corporation

certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of either:

A. [ ] An assignment from the inventor(s) of the patent application identified above. The assignment was recorded in the Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

OR

B. [X] A chain of title from the inventor(s) of the patent application identified above, to the current assignee as shown below:

1. From: James John Hogan, Richard Dana Smith, JoAnn Kop and Sherrol Hoffa McDonough to Gen-Probe Incorporated and ML Technology Ventures  
The document was recorded in the Patent and Trademark Office at Reel 4926, Frame 018-020, or for which a copy thereof is attached.
2. From: ML Technology Ventures to Gen-Probe Incorporated  
The document was recorded in the Patent and Trademark Office at Reel 6057, Frame 434-436 or for which a copy thereof is attached.
3. From: \_\_\_\_\_ to \_\_\_\_\_  
The document was recorded in the Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

[ ] Additional documents in the chain of title are listed on a supplemental sheet.

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[ ] Copies of assignments or other documents in the chain of title  
are attached.

The undersigned has reviewed all the documents in the chain of title  
of the patent application identified above and, to the best of  
undersigned's knowledge and belief, title is in the assignee  
identified above.

The undersigned (whose title is supplied below) is empowered to act on  
behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge  
are true, and that all statements made on information and belief are  
believed to be true; and further, that those statements are made with  
the knowledge that willful false statements, and the like so made, are  
punishable by fine or imprisonment, or both, under Section 1001, Title  
18 of the United States Code, and that such willful false statements  
may jeopardize the validity of the application or any patent issuing  
thereon.

Date: Nov. 6, 1996

Daniel L. Kacian, Ph.D., M.D.

(Name)

Sr. Vice President & Chief Scientific Officer  
(Title)

Daniel L. Kacian  
(Signature)



212/083  
Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Hogan et al.

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ORGANISMS

Group Art Unit 1819

Examiner: Marschel, A

VERIFIED WRITTEN CONSENT OF ASSIGNEE

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

I hereby declare that I am an official empowered to act on behalf of GEN-PROBE INCORPORATED the assignee of the above-identified patent application.

GEN-PROBE INCORPORATED consents to the correction of inventorship as set forth in the accompanying Petition for Correction of Inventorship, requesting that the inventorship of the above-identified application be corrected to include JoAnn Kop and Sherrol Hoffa McDonough as inventors. The present application should list James John Hogan, Richard Dana Smith, JoAnn Kop, and Sherrol Hoffa McDonough as inventors.

I hereby certify that I have the authority to execute this written consent.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application and any patent issuing thereon.

Nov. 6, 1996

Date

Daniel L. Kacian

Signature

Daniel L. Kacian, Ph.D., M.D.

Typed or printed name

Sr. Vice President & Chief Scientific Officer

Title